

REMARKS

Responsive to the lack of unity determination imposed in the outstanding Official Action mailed July 24, 2007, applicants hereby provisionally elect Group I, claims 1-12 and 18-28, with traverse.

As to the first election of species, applicants elect Species A, a polymer compound wherein the terminal functional group is phosphatidyl choline, with traverse. The species reads on claims 1-7 and 10-22.

As to the second election of species, applicants hereby provisionally elect Species F, a polymer compound wherein the polyester is polymerized from trimethylene carbonate, with traverse. Applicants believe that all of the claims read on the elected species.

The grounds for traverse are that the outstanding Official Action fails to satisfy the requirements of PCT Rules 13.1 and 13.2. As the Examiner is aware, PCT Rule 13.1 requires that "an international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." PCT Rule 13.2 dictates that the "requirement of unity invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical features" shall be those technical features that define

a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Thus, PCT Rule 13.2 is art-based. As no such citation has been provided by the Official Action, applicants believe that the lack of unity determination is improper as a matter of law.

Furthermore, the present application describes a new class of polymeric materials, how the polymeric materials can be produced and how the polymeric materials can be applied.

The main issue of the invention is to present new biodegradable polymeric materials that are hemocompatible (alleged Group I). Their structure and synthesis are well described in the application.

Examples of where an object is coated with the polymeric materials are also provided (alleged Group II). Objects that are selected from this listing, and coated with the disclosed polymeric material (Group I), all share a novel common technical feature, namely the polymeric material. Thus, the claimed coated object and the polymeric material will form a unitary invention.

Moreover, while examples where the polymers are used in combination with drugs are given (alleged Group III), the claimed invention does not necessarily relate to a description of an interaction between a drug and a polymer in such a way that the drugs chemical or pharmacological properties are altered. Rather, the claimed invention relates to how the new polymeric

material can be used to encapsulate drugs for delivery purposes. The release of the drug depends on how the drug carrier is designed, i.e. on the disintegration rate of the drug carrier material.

Thus, drug formulations comprising medicaments that are coated/encapsulated with the disclosed polymeric material, the polymer (Group I), the object coated with the polymer (Group II), and polymer in combination with a drug (Group III), all share a novel common technical feature, namely the polymeric material.

As to the first election of species, Species A-O all describe functional end groups that are ionic; cat-, an- or zwitterionic. The functional groups are based on the polar head groups found in phospholipids.

However, the claimed polymeric compound contains at least one biodegradable polyester having a terminal functional group based on hydrophilic moieties of phospholipids.

Accordingly, it cannot be said that a search and examination of species A-O would impose an undue burden on the Patent Office.

The monomers used to produce the polymer compounds A-G are all cyclic esters from organic acids:

- A: ϵ -capric acid
- B: lactic acid
- C: glycolic acid
- D: β -butyric acid

E: β propionic acid

F: carbonic acid

G: combinations of A-F.

They are all polymerized according to the same general reaction mechanism, namely ring opening polymerization (ROP).

All the resulting polymer compounds A-G all contain functional groups (esters/carbonates), in the polymer main chain, that can be hydrolyzed *in vivo*, and thus all resulting polymers A-G are biodegradable. Accordingly, all resulting polymers A-G exhibit the properties stated in the present application as intended and desired.

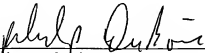
In this regard, applicants believe that a search and examination of all of species A-G fails to place an undue burden on the Patent Office.

In view of the above, applicants respectfully request a search and examination of all the claims in their full scope.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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